REMARKS

Claims 1-7, 9, 11, 13-18, and 24-42, have been withdrawn without prejudice or disclaimer. Applicants have added new claims 43-55. Claims 8, 10, 12, 19-23, and 43-55 are pending.

Claim 8 has been amended to incorporate certain elements from non-elected claims. Claim 8 has also been amended to recite, "wherein the polypeptide has at least one activity characteristic of B7RP1 or CRP1." Support for amended claim 8 can be found in original claim 8 and throughout the specification, for example at page 43, lines 12-22.

Claim 10 has been amended to incorporate certain elements from non-elected claims. Claim 10 has also been amended to recite, "wherein the polypeptide has at least one activity characteristic of B7RP1." Support for amended claim 10 can be found in original claim 10 and throughout the specification, for example at page 43, lines 12-22.

Claim 12 has been amended to recite, "wherein the polypeptide has at least one activity characteristic of B7RP1." Support for amended claim 12 can be found in original claim 12 throughout the specification, for example at page 43, lines 12-22.

Claim 19 has been amended to incorporate certain elements from non-elected claims. Claim 19 has also been amended to recite, "wherein the polypeptide has at least one activity characteristic of B7RP1." Support for amended claim 19 can be found in original claim 19 and throughout the specification, for example at page 43, lines 12-22.

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Claim 20 has been amended so that it does not refer to non-elected claims. Support for amended claim 20 can be found in original claim 20.

Support for claim 43 can be found throughout the specification, for example at page 41, lines 30-34; and Figures 1 through 3.

Support for claim 44 can be found throughout the specification, for example at page 41, lines 30-34; and Figures 1 through 3.

Support for claim 45 can be found throughout the specification, for example at page 42, lines 7-11; page 43, lines 12-22; Figures 1 through 3; and original claim 12.

Support for claim 46 can be found throughout the specification, for example at page 47, lines 23-26; page 43, lines 12-22; and Figures 1 through 3.

Support for claim 47 can be found throughout the specification, for example at page 42, lines 7-11; page 47, lines 23-26; page 43, lines 12-22; Figures 1 through 3; and original claim 12.

Support for claim 48 can be found throughout the specification, for example at page 43, lines 12-22; and Figure12.

Support for claim 49 can be found throughout the specification, for example at page 43, lines 12-22; and Figure12.

Support for claim 50 can be found throughout the specification, for example at page 41, lines 30-34; and Figure12.

Support for claim 51 can be found throughout the specification, for example at page 41, lines 30-34; and Figure12.

Support for claim 52 can be found throughout the specification, for example at page 26, lines 21-22; and Figures 1 through 3.

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Support for claim 53 can be found throughout the specification, for example at page 25, lines 18-23; and Figures 1 through 3.

Support for claim 54 can be found throughout the specification, for example at page 26, line 32, through page 27, line 2; page 43, lines 12-22; and Figures 1 though 3.

Support for claim 55 can be found throughout the specification, for example at page 25, lines 18-23; and Figure 12.

Thus, the claims are fully supported by the application as originally filed and the amendment adds no new matter.

Drawings

The Examiner requested correction to the Brief Description of the Drawings. See Action at page 2. Applicants have amended the Brief Descriptions of the Drawings to reflect the numbering used in the Figures and to describe each individual panel, as requested. The description of Figure 13 was also amended to correct the misidentification of terms listed in the parentheses. The description of Figure 1B was amended to restore a sentence that was inadvertently replaced by ellipsis in a previous amendment. The amendments add no new matter.

Specification

The Examiner requested that the title be amended. See Action at page 3. The title has been amended to remove the word "novel," as requested. Applicants respectfully remind the Examiner of the obligation to examine subject matter not elected in a generic claim, if the elected subject matter is patentable. Pending claim 8 is a generic claim that includes certain CRP-1 polypeptides. Accordingly, Applicants ask that the Examiner hold the request to amend the title in abeyance until allowable subject matter is determined.

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The Examiner objected to the Abstract. A replacement Abstract is enclosed.

Claim Objections

The Examiner objected to claims 8, 10, and 19-23 as being dependant from non-elected claims. See Action at page 3. Claims 8, 10, 19, 20, and 22 have been amended to incorporate certain elements from non-elected claims. None of the present claims, as amended, depends from a non-elected claim.

The Examiner objected to claims 12, 19, 20, and 22 for certain informalities. See Action at page 3. Those informalities have been corrected.

Rejections Under 35 U.S.C. § 112, first paragraph (written description)

The examiner rejected claims 8, 10, 12, and 19-23, under 35 U.S.C. § 112, first paragraph as allegedly "containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention." Action at page 4. Applicants respectfully traverse this rejection. The Examiner discussed certain terms used in the claims which will be addressed in turn.

A) "Variants[1]"

The examiner rejected certain claims that "recite a genus of polypeptides but do not require that the instant polypeptides share any testable functional activity, a feature deemed essential to the instant invention." Action at page 4. Applicants respectfully traverse this rejection and disagree that functional activity is "essential to the instant invention." Certain of the original claims did not recite activity. All of the present claims

[1] The Examiner stated that the claims recite "'variant' language, including a 'derivative.'" Action at page 4. "Variants" are discussed in the specification at page 42, lines 25-36. "Derivatives" are discussed at page 43, lines 1-11. Though a polypeptide may be both a variant and a derivative, it is inaccurate to say that the term "variant" includes "derivatives."

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subject to this rejection recite activity. Accordingly, all of the claims that recite a derivative or a percent identity also recite an activity. Thus, the Examiner's rejection is moot.

The Examiner stated that, "[i]n the absence of a particular testable function and some structural basis for that function that must be maintained by members of the genus, the claimed invention is not described in such a way as to reasonably convey to on of ordinary skill in the art that the inventor, at the time the application was filed, had possession of the invention." Action at page 4. Polypeptides that are at least 70% identical to a polypeptide having a particular sequence identification number recited in the claims are specifically structurally related to such sequences. Thus, adequate structure is provided and the claimed invention is adequately described.

B) "Polypeptides Comprising Fragments"

The Examiner rejected certain claims alleging that "[f]ragment language that encompasses open (comprising) claim language permits unidentified flanking sequence to be added to the recited subsequence of a particular SEQ ID NO and so does not allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described." Action at page 5. Applicants respectfully traverse this rejection.

To support this rejection, the Examiner cited *Vas-Cath Inc. v. Mahurkar,* 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In that case, the Federal Circuit held that the lower court "erred in applying a standard that essentially required the drawings [relied upon by the applicant] to *necessarily exclude* all diameters other than those within the claimed range." *Id.* at 119 (emphasis original). Rather, the Court said, the "proper test is whether the drawings conveyed with reasonable clarity to those of ordinary skill that [the applicant] had invented the catheter recited in the claims." *Id.* Similarly, the test

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here is not whether the specification describes every possible flanking sequence. Rather, the test is whether the specification conveys the claimed invention with "reasonable clarity to those of ordinary skill." *Id.* The specification adequately conveys the claimed invention to one of ordinary skill.

Furthermore, the transitional phrase "comprising," which "leaves the claim open for the inclusion of unspecified ingredients even in major amounts," is permitted. See The Manual of Patent Examining Procedure, Eighth Edition, August 2001 (MPEP) § 2111.03. Accordingly, claims that recite the transitional phrase "comprising" always encompass material that is not described in the specification. The Examiner has provided no support for a conclusion that the term "comprising" renders a claim unpatentable under the written description requirement of § 112, first paragraph. Therefore, the fact that claims 8, 10, 12, and 19-23 encompass "unidentified flanking sequence" because they recite the transitional phrase "comprising" is not a proper basis for rejection.

C) "Allelic Variants and Splice Variants"

The Examiner rejected certain claims that recited "allelic variants" and "splice variants." See Action at page 5. Solely to expedite prosecution, Applicants have amended the claims so that none of the present claims specifically recite the terms "allelic variant" or "splice variant." Thus, the Examiner's rejection is moot. Consequently, Applicants do not address the contentions made by the Examiner. However, Applicants do not acquiesce to the Examiner's rejection and reserve the right to add claims specifically reciting allelic variants and/or splice variants.

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D) An "ortholog" of B7-RP1 polypeptide

The examiner rejected certain claims that recited an "ortholog." See Action at page 5. Solely to expedite prosecution Applicants have amended the claims so that none of the present claims specifically recite the term "ortholog." Thus, the Examiner's rejection is moot. Consequently, Applicants do not address the contentions made by the Examiner. However, Applicants do not acquiesce to the Examiner's rejection and reserve the right to add claims specifically reciting orthologs.

Applicants respectfully request reconsideration and withdrawal of the § 112, first paragraph rejection based on the written description requirement.

Rejections Under 35 U.S.C. § 112, first paragraph (enablement)

The Examiner rejected claims 8, 10, 12, and 19-23 alleging that those claims were not reasonably enabled by the specification. See Action at page 6. Applicants will again address the Examiner's remarks regarding certain terms.

A) "Variant Polypeptides"

The Examiner alleged that "the experimentation left to those skilled in the art to determine which 'variant' sequences would still result in polypeptides having the same function as the human and mouse B7-RP1 polypeptides disclosed in the specification as filed is unnecessarily, and improperly, extensive and undue." Action at page 7. Applicants respectfully traverse this rejection.

First, it is noted that none of the rejected claims recite the term "variant."[2] Claims 8, and 10 do recite "a polypeptide that are at least about 70 percent identical" to a polypeptide having a particular sequence identification number. Solely to expedite

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[2] Claims 8, 10, and 12 did recite the terms "allelic variants" and "splice variants," however the Examiner addressed those terms separately from "variants." See Action at page 8.

prosecution and without acquiescing to the Examiner's arguments, claim 8 has been amended to recite "wherein the polypeptide has at least one activity characteristic of B7RP1 or of CRP1." Solely to expedite prosecution and without acquiescing to the Examiner's arguments, claim 10 has been amended to recite "wherein the polypeptide has at least one activity characteristic of B7RP1." Guidance for such claims is provided. See, e.g., page 45, line 11, through page 47, line 34.

Applicants assert that it is not necessary that one skilled in the art be able to predict precisely which changes in a polypeptide will not affect activity, because modifying a polypeptide and testing it for activity does not involve undue experimentation. First, applicants assert that it was within the skill in the art at the time the application was filed to use standard molecular biology techniques to make fragments of a polypeptide comprising the amino acid sequence of particular sequence identification numbers or encoded by nucleotide sequences of particular sequence identification numbers. Second, applicants assert that it was within the skill in the art at the time the application was filed to make polypeptides that are at least about 70% identical to those polypeptides or fragments. Finally, applicants assert that it was within the skill in the art at the time the application was filed to determine if such polypeptides or polypeptide fragments have at least one activity characteristic of B7RP1 or CRP1.

Applicants assert that to make those polypeptides or polypeptide fragments and determine their activity does not constitute undue experimentation. Rather, that process is analogous to the process of making and screening monoclonal antibodies, which the Federal Circuit found not to be undue experimentation in *In re Wands*, 858 F.3d 731, 8 U.S.P.Q.2d 1400 (Fed. Cir.1988). In that case, the court held that the test for undue

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experimentation "is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine...." *Id.* at 737.

Applicants therefore assert that making and screening polypeptides and polypeptide fragments also does not involve undue experimentation.

B) "Fragments Comprising"

The Examiner rejected claims that "recite in various forms polypeptides comprising 'fragments' of certain number of amino acids residues of the various SEQ ID NOS." Action at page 7. The Examiner alleged that "before the skilled artisan can make polypeptides comprising 'fragments' with additional flanking sequence, guidance is required with respect to the identity of those flanking sequences." Applicants respectfully traverse this rejection.

The Examiner again focused on the transitional phrase "comprising," stating that that phrase "opens the claim up to the inclusion of additional residues of undisclosed identity and number flanking the recited 'fragment.'" Action at page 7. As discussed previously, that transitional phrase, which always leaves the claim open to additional unknown material, is permitted. Accordingly, the fact that a claim encompasses additional unknown flanking sequences is not a proper basis for a rejection.

Furthermore, the specification provides guidance for polypeptides comprising fragments. For example, the specification describes the construction of a B7-RP1-Fc fusion protein in which B7-RP1 polypeptide was fused to the Fc region of IgG1. See Specification at page 31, lines 7-30 and Example 7. One skilled in the art will readily appreciate that such a fusion protein could be made with a fragment of a B7-PR1 polypeptide. Additionally, such a fusion protein could be made using a protein other than the Fc region of IgG1.

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C) "Allelic Variants" and "Splice Variants"

The Examiner rejected claims reciting the terms "allelic variants" and "splice variants" as allegedly not enabled. Action at page 7. Solely to expedite prosecution, Applicants have amended the claims such that none of the present claims specifically recite "allelic variant" or "splice variant." Thus, the Examiner's rejection is moot. Consequently, Applicants do not address the contentions made by the Examiner. However, Applicants do not acquiesce to the Examiner's rejection and reserve the right to add claims specifically reciting allelic variants and/or splice variants.

D) An "Ortholog" of B7-RP1 polypeptide

The examiner rejected certain claims that recited an "ortholog." See Action at page 8. Solely to expedite prosecution, Applicants have amended the claims such that none of the present claims specifically recite "ortholog." Thus, the Examiner's rejection is moot. Consequently, Applicants do not address the contentions made by the Examiner. However, Applicants do not acquiesce to the Examiner's rejection and reserve the right to add claims specifically reciting orthologs.

Rejections Under 35 U.S.C. § 112, second paragraph

The Examiner rejected claims 12 and 19-23 under 35 U.S.C. § 112, second paragraph, for allegedly "failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention." Action at page 12. The Examiner pointed out that the terms "allelic variant" and "alternative splice variant" refer to nucleic acids, not to the polypeptides encoded by such nucleic acids. Those terms have been deleted from claims 12, 19, 20, and 22. Claim 21 depends from claim 20. Claim 23 depends form claim 22. Thus, none of the rejected claims recites "allelic variants" or

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"alternative splice variants," and the Examiner's rejections under 35 U.S.C. § 112, second paragraph, are moot.

Rejections Under 35 U.S.C. § 102

The Examiner rejected claims 8, 10, 12, and 20 as allegedly "being anticipated by Ishikawa et al (DNA Res. June 1998; 5:169-176, see entire document) as evidenced by GenBank Accession No. AB014553 (released 06 Feb 1999)." Action at page 9.

First, as the Examiner pointed out, SEQ ID NOs. 6, 7, 11, and 12 were disclosed in parent application USSN 09/244,448, filed February 3, 1999, as were SEQ ID NOs. 1 and 2. Thus, the priority date for those sequences is February 3, 1999, three days before the release of GenBank Accession No. AB014553 on February 6, 1999. Therefore, that GenBank data is not prior art against claims to sequence ID NOs. 1, 2, 6, 7, 11, or 12. Solely to expedite prosecution and without acquiescing to any of the Examiner's contentions, Applicants have amended claims 8, 10, 12, and 19. Those amended claims do not recite SEQ ID NOs: 16 or 17.

Second, Ishikawa cannot anticipate the current claims. For a reference to anticipate it must disclose every element of the claim. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.,* 802 F.2d 1367, 1379, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986). Moreover, the reference must be enabling. *See* MPEP § 2121.01. "A reference contains 'enabling disclosure' if the public was in possession of the claimed invention before the date of invention." Id.

Ishikawa broadly discusses 100 proteins isolated from human brain cDNA libraries. It provides a few characteristics of those 100 proteins, such as length of cDNA and apparent molecular weight. See Table 1. Ishikawa also categorizes the 100 proteins "based on homologies to known proteins." As the Examiner pointed out,

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Ishikawa notes that KIAA0653 is 32.9% identical to "CD80-like protein precursor." See Table 2. That scant information is not sufficient to enable one of skill in the art to isolate or identify a polypeptide of claims 8, 10, 12 or 20. Accordingly, Ishikawa did not "put the public in possession of the claimed invention" at the time of the filing of the application. Therefore, Ishikawa is not an enabling disclosure and cannot anticipate the present claims. It is noted that although later-disclosed data can be used to establish inherency, an anticipating reference must be fully enabling at the time the application is filed. See MPEP §§ 2121, 2131, and 2124.

Rejections Under 35 U.S.C. § 103

The Examiner rejected claims 19-23 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Ishikawa in view of Linsley . See Action at page 10. Each of those claims included a polypeptide of claim 10, which the Examiner rejected as allegedly being anticipated by Ishikawa. The Examiner cited Linsley as allegedly showing certain additional elements of the rejected claims.

For at least the reasons stated above, Ishikawa does not anticipate claim 10. Further, Linsley does not remedy the deficiencies of Ishikawa. Because the polypeptide of claim 10 is patentable over Ishikawa in view of Linsley, claims 19-23 are likewise patentable. Moreover, Applicants need not address the Examiner's contentions with respect to other elements of those claims. By not addressing those contentions, Applicants in no way acquiesce to those contentions.

Conclusion

Applicants respectfully assert that the application is in condition for allowance. If the Examiner does not consider the application to be in condition for allowance, the

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Applicants request that the Examiner call the undersigned ((650) 849-6601) to arrange an interview prior to taking action.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: April 30, 2003

By: _____
Clifford E. Ford
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